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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 08/479,997      | 06/07/1995  | DEAN ENGELHARDT      | ENZ-5(D6)(C2        | 8799             |

28170 7590 10/08/2002

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| EXAMINER |
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SPIEGLER, ALEXANDER H

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| ART UNIT | PAPER NUMBER |
|----------|--------------|

1637

DATE MAILED: 10/08/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

08/479,997

Applicant(s)

ENGELHARDT ET AL.

Examiner

ALEXANDER SPIEGLER

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on Amendment N 05/28/02.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 576-825 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) See Continuation Sheet is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☒ Claim(s) 814-816 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Continuation of Disposition of Claims: Claims allowed are

577,581,583,597,601,603,618,622,624,638,642,644,659,663,665,678,682,684,702,704,717,721,723 and 736- 825.

Continuation of Disposition of Claims: Claims rejected are 576,578-580,582,584-596,598-600,602,604-617,619-

621,623,625- 637,639- 641,643,645-658,660-662,664,666-677,679-681,683,685- 697,699-701,703,705- 716,718-720,722 and 724-735.

### DETAILED ACTION

1. This action is in response to Paper No. 51, filed on May 28<sup>th</sup>, 2002. Currently, newly added claims 576-825 are pending. All arguments have been full considered and thoroughly reviewed, but are deemed not persuasive for the reasons that follow. This action is based on rejections necessitated by Applicants' amendments, and therefore, this action is made FINAL. Any objections and rejections not reiterated below are hereby withdrawn. Specifically, the 102 and 103 rejections (of the previous office action) have been withdrawn, in response to Applicants' amendments to the claims, as well as, the declarations of Dr. Alexander A. Waldrop, III and Dr. Charles W. Parker.

### *Information Disclosure Statement*

2. The information disclosure statement of Paper No. 51 complies with U.S.C. 1.97, 1.98, and M.P.E.P. 609, and has been considered.

### *Claim Objections*

3. ✓ Claims 814-816 are objected to because of the following informalities:

A) Claims 814-816, depend from claim 454, which has been canceled.

Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

✓  
5. Claims 577, 597, 618, 638, 659, 678, 698, 717, 737, 756, 776, 795 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 577, 597, 618, 638, 659, 678, 698, 717, 737, 756, 776, 795 are indefinite over the recitation of "self-signaling or self-indicating or self-detecting" because it is not clear what is meant by this recitation. (i.e. it is not clear as to how a Sig can be considered be self-signaling or self-indicating or self-detecting). For example, a fluorescent compound needs a specific wavelength of light to excite the compound to fluoresce and optical detection system to detect emitted fluorescence, therefore it is not clear as to how a Sig (for example a fluorescent compound) could be self-signaling or self-indicating or self-detecting. In other words, it is not clear as to how a Sig can be considered self-signaling or self-indicating or self-detecting without the use of an additional element to aid in the signaling, indicating or detecting of the Sig.

#### **Applicants Arguments**

Applicants' argue that a reader skilled in the art would readily comprehend the meaning of the above terms. Furthermore, Applicants identity 4 US patents and 4 scientific publications to demonstrate that the term "self-indicating" is used and recognized in the art.

#### **Response to Applicants Arguments**

Applicants arguments have been considered but are not persuasive for the following reasons:

1) Given the lack of a definition in the specification for "self-signaling", "self-indicating" or "self-detecting", it is not clear that a reader skilled in the art would readily comprehend the meaning of these terms. Claim 577, states, "wherein Sig is or renders...self-detecting", does this mean that a fluorescent label could detect itself?

2) The cited US patents and literature articles, while using the term "self-indicating", have nothing to do with the claimed invention. The claimed invention is drawn to a Sig that is part of a modified nucleotide of a polydeoxyribonucleotide, the cited references do not involve

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modified nucleotides. Furthermore, these references do not use the terms, "self-signaling" or "self-detecting", and therefore, do help render these terms definite.

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. ✓ Claims 581, 583, 601, 603, 622, 624, 642, 644, 663, 665, 682, 684, 702, 704, 721, and 723 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These claims include the recitation of "wherein chemical linkage comprises or includes an olefinic bond at the alpha-position relative to the point of attachment". The only reference to a "chemical linkage" is the Sig is covalently attached to the PM directly or through a chemical linkage. There is no support in the specification, for where the Sig is covalently attached to the PM directly or through a chemical linkage, "wherein chemical linkage comprises or includes an olefinic bond at the alpha-position relative to the point of attachment". This recitation is considered new matter.

Applicants argue that the new recitation is properly supported by Applicant's original disclosure, page 3, lines 2-3 from bottom of the page; page 11, line 7 in the second paragraph; and originally filed claim 78.

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However, these references to the specification do not describe the Sig is covalently attached to the PM directly or through a chemical linkage, "wherein chemical linkage comprises or includes an olefinic bond at the alpha-position relative to the point of attachment". These references actually teach that the position in question (i.e. alpha-position relative to the point of attachment) is relative to the point of attachment to the Base, not the Sig-PM attachment, as instantly claimed.

8. ✓ Claims 736-825 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

These claims recite, "Sig being covalently attached to PM through a chemical linkage comprising a polypeptide or a protein", which is not supported in the specification, and therefore, constitutes new matter.

If Applicants' traverse this rejection, Applicants' should specifically identify (by page and line number), where the specification provides support for these claims.

### ***Conclusion***

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

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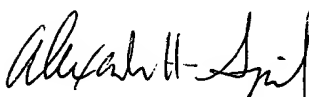
the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


*Correspondence*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander H. Spiegler whose telephone number is (703) 305-0806. The examiner can normally be reached on Monday through Friday, 7:00 AM to 3:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014. Applicant is also invited to contact the TC 1600 Customer Service Hotline at (703) 308-0198.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
Alexander H. Spiegler  
October 1, 2002

  
KENNETH R. HORLICK, PH.D  
PRIMARY EXAMINER

10/1/02